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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Comment	10/593,990	PEYTAVI, REGIS				
Office Action Summary	Examiner	Art Unit				
	Sharon Pregler	1797				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on						
	- [.] action is non-final.					
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	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
dissect in assertation with the practice and in E.	x parte quayre, 1000 0.D. 11, 10	0.0.210.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-141</u> is/are pending in the application	☑ Claim(s) <u>1-141</u> is/are pending in the application.					
4a) Of the above claim(s) 41,48,49 and 59-141	4a) Of the above claim(s) 41,48,49 and 59-141 is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-40,42-47 and 50-58</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	· <u> </u>					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
, —						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/23/07 & 1/15/10.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	te				

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1. <u>Claims 17, 28, 47, 57, & 58</u> are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Regarding claims 17 & 28 the term "valve-cavity" is unclear.
 - b. Regarding claim 47, the term "being adapted to be actuated" is unclear.
 - c. Regarding claim 57, the term "auxiliary microfluidic flow cell" is unclear.
 - d. Regarding claim 58, the term "support cavity" is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. <u>Claims 1-4, 7-15, 19, 29-36, 38 & 47</u> are rejected under 35 U.S.C. 102(b) as being anticipated by Mathies US Pre-Grant Publication.
- 3. **Regarding claims 1, 2, 7, & 12 Mathies teaches a** microfluidic flow cell (top planar member 224, [0087], figure 6-6b) for removably interfacing with a removable-member (bottom planar member 222, substrate may be attachable and removable from the device [0012]) for performing a reaction therebetween ([0011]), said microfluidic flow cell comprising:
- 4. at least one reaction portion or cavity (regarding claim 7) (reaction chamber 225/226, figure 6-7, [0011]-[0012], [0023], [0088], & [0103]) defining with the removable-member a reaction chamber (forming within

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[0012]) when said microfluidic flow cell and said removable-member are in an interfaced position thereof; and

- 5. at least one fluid-receiving portion, (multiple reservoirs, multiple introduction channels, [0089]) or conduit (regarding claim 2) formed within said microfluidic flow cell (regarding claim 12) (sample introduction channel 230, figure 6 [0089]) formed within said microfluidic flow cell (regarding claim 12) (top planar member 224, [0087], figure 6-6b), for receiving a fluid therein and being in fluid communication with said reaction chamber (connected to reaction chamber [0023], [0089]);
- 6. a dispensing portion *(channel 234)* in fluid communication with said reaction chamber, said dispensing portion comprising a dispensing channel *(channel 234)* formed within said microfluidic cell;
- 7. wherein when in said interfaced position, said microfluidic flow cell is adapted to allow for the fluid in said fluid-receiving portion to flow to said reaction chamber ([0028], [0087]-[0089]). (See figures 6-7, [0011]-[0023], & [0088]-[0103]).
- 8. **Regarding claims 3-4, & 14 Mathies teaches the** microfluidic flow cell according to claim 1, further comprising a plurality of separate fluid-receiving portions (regarding claim 3) (See 230 in figure 6 and channel 232, [0089]) and separate conduits (regarding claim 4) formed within said microfluidic flow cell (regarding claim 14) (See 230 in figure 6 and channel 232, [0089]) each receiving a respective fluid, each of said separate fluid-receiving portions being in fluid communication with a common said reaction chamber (chamber 235, figure 6). (See figure 6, [0089]).
- 9. **Regarding claim 8, Mathies teaches the** microfluidic flow cell according to claim 7, wherein said cavity comprises a structure selected from the group consisting of indentations and at least one groove (See [0023]).
- 10. **Regarding claim 9, Mathies teaches the** microfluidic flow cell according to claim 1, wherein said fluid-receiving portion comprises a reagent chamber (chamber 225, figure 6), said fluid comprising a reagent ([0128]).
- 11. **Regarding claim 10, Mathies teaches the** microfluidic flow cell according to claim 1, wherein said fluid-receiving portion comprises a fluid-receiving chamber (reservoirs 240, 242l 244, figure 6, [0089]) formed within

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said microfluidic flow cell (top planar member 224, [0087], figure 6-6b). (See figure 6, [0089]).

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- 12. **Regarding claim 11, Mathies teaches the** microfluidic flow cell according to claim 1, wherein said fluid-receiving portion comprises a fluid-receiving cavity (reservoirs 240, 242l 244, figure 6, [0089]) defining a fluid-receiving chamber with said removable-member when said microfluidic flow cell and said removable-member are in said interfaced position (may from chamber or cavities in [0012]). (See figure 6, [0012], & [0089]).
- 13. **Regarding claim 13, Mathies teaches the** microfluidic flow cell according to claim 2 further comprising a conduit cavity (within channel 230), said conduit-cavity defining said conduit when said microfluidic flow cell and said removable-member are in said interfaced position (See [0012]). (See figure 6, [0012]).
- 14. **Regarding claim 15, Mathies teaches the** microfluidic flow cell according to claim 3, wherein at least one of said plurality of conduits *(channels 230, 232)* is defined by a conduit in said microfluidic flow cell when said microfluidic flow cell and said removable member are in said interfaced position *(See [0012])*.
- 15. **Regarding claim 19, Mathies teaches the** microfluidic flow cell according to claim 18, further comprising a common channel-cavity (within channel 230), said common channel-cavity defining said common channel when said microfluidic flow cell and said removable-member are in said interfaced position ([0012]). (See figure 6, [0012], & [0088]).
- 16. **Regarding claim 29, Mathies teaches the** microfluidic flow cell according to claim 1 further comprising a dispensing portion *(channel 234)* in fluid communication with said reaction chamber. *(See figures 1-2, [0089])*
- 17. **Regarding claim 30, Mathies teaches the** microfluidic flow cell according to claim 1, wherein said dispensing portion comprises a dispensing channel (channel 234), said microfluidic flow cell further comprising a dispensing channel-cavity (within channel 234), said dispensing channel-cavity defining said dispensing channel when said microfluidic flow cell and said removable-member are in said interfaced position (See [0012]). (See figure 6, [0012] & [0088-89]).

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18. **Regarding claim 31, Mathies teaches the** microfluidic flow cell according to claim 1, wherein said microfluidic flow cell comprises hydrophobic material (plastics & silicon based materials [0087] & [0138]).

- 19. **Regarding claim 32, Mathies teaches the** microfluidic flow cell according to claim 1, wherein said microfluidic flow cell comprises a substrate (See figure 6).
- 20. **Regarding claims 33 & 34, Mathies teaches** microfluidic flow cell according to claim 32, wherein said substrate comprises elastomeric material (regarding claim 35) (See [0087]) said elastomeric material comprises PDMS (regarding claim 36) (plastics & silicon based materials [0087]).
- 21. **Regarding claim 35, Mathies teaches the** microfluidic flow cell according to claim 1, wherein said removable-member comprises a support (bottom planar member 222, substrate may be attachable and removable from the device [0012]) for performing a reaction thereon (See figure 6).
- 22. **Regarding claim 36 Mathies teaches the** microfluidic flow cell according to claim 35, wherein said support comprises hydrophobic material (plastics & silicon based materials [0087] for example PDMS, a well known material to fabricate microfluidic chips is inherently hydrophobic).
- 23. **Regarding claim 38, Mathies teaches the** microfluidic flow cell according to claim 37, wherein said support comprises glass ([0087]).
- 24. **Regarding claim 47, Mathies teaches the** microfluidic flow cell according to claim 1 being adapted to be actuated so as to provide for the fluid in said fluid-receiving portion to flow to said reaction chamber. These actuations include actuation forces such as electrokinetics ([0011]), electrophoresis ([0011], [0013]), gravity ([0019], [0075), mechanical micropump force ([0019]), capillary force ([0011], [0019]), thermal force ([0098]), positive and negative displacement force ([0075]), ([0090]), pneumatic drive force ([0068]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. <u>Claims 5, 16-18, 37, 50-53, & 56-58</u> are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies US Pre-Grant Publication (hereinafter "Mathies").

- 26. **Regarding claims 5, & 16-18 Mathies teaches the** microfluidic flow cell according to claim 4 within the microfluidic flow cell (regarding claim 16), ([0028]), but does not explicitly teach said plurality of separate conduits meet at a valve for fluid communication therewith, said valve being in fluid communication with said common reaction chamber (chamber 225)(regarding claim 5) formed within said microfluidic flow cell (regarding claim 18) (See figure 6) valve-cavity (regarding claim 17) within the microfluidic cell (regarding claim 27).
- 27. However, Mathies teaches control within the microfluid capillaries comprising the use of valves. (See [0028] & [0075]).
- 28. It is within ordinary skill in the art and would have been obvious to place a valve in the conduits, and channels above for the benefit of controlling fluid flow in the microfluidic device.
- 29. **Regarding claim 37,** this claim is regarded as intended use and does not add structural weight to the apparatus claim.
- 30. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior

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art structure is capable of performing the intended use, then it meets the claim.

- Regarding claims 50-53 & 56, Mathies teaches the microfluidic flow cell according to claim 1 but does not explicitly teach at least one vent ([0019]), said vent being in fluid communication with the ambient environment and with said fluid receiving portion (regarding claim 51), ([0028]), between ambient environment and reaction chamber (regarding claim 50), between ambient environment and conduit (claim 52) and ambient environment and valve (regarding claim 53) ([0060]) and between ambient environment and dispensing portion. (See figure 1, [0019], [0028], [0058], [0060]).
- 32. Mathies teaches control within the microfluid capillaries comprising the use of vents. (See figure 1, 9 [0019], [0028], [0060] & [0075]) for the benefit of controlling fluid flow through positive and negative pressure ([0060]).
- 33. It is within ordinary skill in the art and would have been obvious to place a vent between the environment and reaction chamber, environment and fluid receiving portion, environment and conduit, environment and valve, and environment and dispensing portion, above for the benefit of controlling fluid flow in the microfluidic device through positive and negative pressure.
- 34. **Regarding claim 57, Mathies teaches the** microfluidic flow cell according to claim 1, wherein said removable member comprises an auxiliary microfluidic flow cell (see figure 6).
- 35. **Regarding claim 58, Mathies teaches the** microfluidic flow ceil according to claim 1, wherein said removable-member comprises a support (bottom planar member 222, substrate may be attachable and removable from the device [0012]) comprising a support cavity (within bottom planar member 222) defining said reaction chamber when in said interfacing position (see [0012]), said reaction cavity comprising a fluid outlet (outlet in [0073]) in communication with said reaction chamber. (See [0012], Figure 6, [0073]).
- 36. <u>Claims 6, 20-28, 54 & 55</u> are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies US Pre-Grant Publication in view of Parce et al. US Patent 5,869,004 (hereinafter "Parce").

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37. **Regarding claim 6 Mathies teaches the** microfluidic flow cell according to claim 5, wherein said fluid communication between said reaction chamber and said valve ([0028] & [0075]) but does not teach the common channel.

- 38. However in the analogous art of microfluidics, Parce teaches a common channel, (main channel 104, figure 1) with channel-cavity (within main channel 104) that are in fluid connection with a series of parallel channels (122, 124, 126, 128...) with a series of fluid sources (106, 110, 112, 114...) that terminate at an end chamber (reservoir 108) formed within said microfluidic flow cell (regarding claim 23) (structure 102)(See figure 1, for the benefit of mixing a series of reactants or fluids to be collected at a terminus (See column 7 lines 20-45).
- 39. Therefore it would have been obvious to one of ordinary skill in the art to rearrange the channels of Mathies and incorporate a the fluidic geometry of Parce for the benefit of mixing a series of reactants or fluids to be collected at a terminus.
- 40. Mathies teaches control within the microfluid capillaries comprising the use of valves. (See [0028] & [0075]).
- 41. It is within ordinary skill in the art and would have been obvious to place a valve in the channels above for the benefit of controlling fluid flow in the microfluidic device.
- 42. **Regarding claim 20 & 23-24, Mathies teaches the** microfluidic flow cell according to claim 1, further comprising a plurality of separate fluid-receiving portions (reservoirs 240, 242) but does not teach each said fluid-receiving portion of said plurality being in fluid communication with a common channel, channel-cavity (regarding claim 24) said common canal being in communication with said reaction chamber. (Reservoirs 240, channel 230, and chamber 225 are fluidically connected, through channels 230/232, figure 6).
- 43. However in the analogous art of microfluidics, Parce teaches a common channel, (main channel 104, figure 1) with canal-cavity (within main channel 104) that are in fluid connection with a series of parallel channels (122, 124, 126, 128...) with a series of fluid sources (106, 110, 112, 114...) that terminate at an end chamber (reservoir 108) formed within said microfluidic flow cell (regarding claim 23) (structure 102)(See figure 1, for the benefit of

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mixing a series of reactants or fluids to be collected at a terminus (See column 7 lines 20-45).

- 44. Therefore it would have been obvious to one of ordinary skill in the art to rearrange the channels of Mathies and incorporate the fluidic geometry of Parce for the benefit of mixing a series of reactants or fluids to be collected at a terminus.
- 45. **Regarding claims 21, 25 & 26 Mathies teaches the** microfluidic flow cell according to claim 20, but does not explicitly teach a pair of elongate bores meeting at a common part of said common canal (regarding claim 21) are formed within said microfluidic flow cell (regarding claim 25) wherein said elongate bored are formed by complementary elongate bore portions defined by said microfluidic flow cell and said removable-member when in said interfaced position (regarding claim 26).
- 46. In the analogous art of microfluidic devices Parce teaches a common channel, (main channel 104, figure 1) that are in fluid connection with a series of bores (parallel channels 122, 124, 126, 128...) with a series of fluid sources (106, 110, 112, 114...) that terminate at an end chamber (reservoir 108) formed within said microfluidic flow cell (regarding claim 23) (structure 102)(See figure 1, for the benefit of mixing a series of reactants or fluids to be collected at a terminus (See column 7 lines 20-45).
- 47. Therefore it would have been obvious to one of ordinary skill in the art to rearrange the channels of Mathies and incorporate the fluidic geometry of Parce for the benefit of mixing a series of reactants or fluids to be collected at a terminus.
- 48. **Regarding claims 22, 27, & 28 Mathies teaches the** microfluidic flow cell according to claim 21, but does not explicitly teach that said common part comprises a valve (regarding claim 22), wherein the valve (regarding claim 27, and valve-cavity (regarding claim 28), is formed within the microfluidic flow cell, said valve-cavity defining said valve when said microfluidic flow cell and said removable-member are in said interfaced position.
- 49. However, Mathies teaches control within the microfluid capillaries comprising the use of valves. (See [0028] & [0075]) for the benefit of controlling fluid flow in the microfluidic device and actuation through an external source.

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50. It is within ordinary skill in the art and would have been obvious to place a valve in the microfluidic device and form a valve-cavity and environment above for the benefit of controlling fluid flow in the microfluidic device and actuation through an external source.

- 51. **Regarding claims 54 & 55, Mathies teaches** the microfluidic flow cell according to claim 2, further comprising at least one vent, but does not teach said vent being in fluid communication with the ambient environment and with said common canal.
- 52. However in the analogous art of microfluidics, Parce teaches a common channel, (main channel 104, figure 1) with canal-cavity (within main channel 104) that are in fluid connection with a series of parallel channels (122, 124, 126, 128...) with a series of fluid sources (106, 110, 112, 114...) that terminate at an end chamber (reservoir 108) formed within said microfluidic flow cell (regarding claim 23) (structure 102)(See figure 1, for the benefit of mixing a series of reactants or fluids to be collected at a terminus (See column 7 lines 20-45).
- 53. Therefore it would have been obvious to one of ordinary skill in the art to rearrange the channels of Mathies and incorporate a the fluidic geometry of Parce for the benefit of mixing a series of reactants or fluids to be collected at a terminus.
- 54. Mathies teaches control within the microfluid capillaries comprising the use of vents. (See figure 1, 9 [0019], [0028], [0060] & [0075]) for the benefit of controlling fluid flow through positive and negative pressure ([0060]).
- 55. It is within ordinary skill in the art and would have been obvious to place a vent in the common canal and environment of Parce above for the benefit of controlling fluid flow in the microfluidic device through positive and negative pressure.
- 56. <u>Claims 39-40, & 42-44</u> are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies US Pre-Grant Publication in view of Chen et al. US Pre-Grant Publication 2003/0087292 (hereinafter "Chen").
- 57. **Regarding claims 39 & 40, Mathies teaches the** microfluidic flow cell according to claim 1, but does not teach said support comprising a microarray (claim 39) with bioprobe spots (regarding claim 40).

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- 58. In the analogous art of microfluidics, Chen teaches a substrate with a microarray with individual probe spots, (See Chen figures 1-2, [0004-5]), for the benefit of targeting molecules within a small area ([0005].
- 59. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the microarray and probe spots with the substrate of Mathies for the benefit of targeting molecules within a small area.
- 60. **Regarding claims 42 Mathies teaches the** microfluidic flow cell according to claim 39 further comprising a plurality of fluid-receiving portions (multiple reservoirs, multiple introduction channels, [0089]) and a plurality of channels in fluid communication therewith (channels 230 & 232), said channels being in communication with said reaction chamber (figure 6). (See figure 6, [0012], [0088-89]).
- 61. **Regarding claims 43 & 44, Mathies teaches the** microfluidic flow cell according to claim 42, wherein said plurality of channels access individual spots of said microarray (regarding claim 43) and individual groups of spots of said microarray (regarding claim 44).
- 62. In the analogous art of microfluidics, Chen teaches an array of probes deposited on a surface of the substrate; and a cover having a channel (figure 42 shows other embodiments of the channel structure including pluralities of channels) being coupled to the substrate such that a target fluid flowing through the channel cavity contacts each probe in the array of probes ([0014]) for the benefit of targeting molecules within a small area ([0004]). (See Chen [0004-5], [0014-5], [0070-73] Figures 1-2 & 42).
- 63. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the channels with the microarray and probe spots with the substrate of Mathies for the benefit of targeting molecules within a small area.
- 64. <u>Claims 45 & 46</u> are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies US Pre-Grant Publication in view of Guigan US Patent 4,788,154 (hereinafter "Guigan").
- 65. **Regarding claim 45 & 46, Mathies teaches** the microfluidic flow cell according to claim 1, but does not teach an enclosure (regarding claim 45) that comprises a removable seal (regarding claim 46.

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66. In the analogous art of microfluidic devices, Guigan teaches a removable cover (*lid 18, figure 2*) for the benefit of removing and reattaching the cover to the device for analysis or cleaning.

67. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the cover of Guigan with the device of Mathies for the benefit of removing and reattaching the cover to the device for analysis or cleaning.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Pregler whose telephone number is (571)270-5051. The examiner can normally be reached on Mon - Thurs 8am-5pm & Fri 8am-12pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Pregler/ Examiner, Art Unit 1797 /Jill Warden/ Supervisory Patent Examiner, Art Unit 1797